K123771

Kyphon® Express™ II Inflatable Bone Tamp
510(k) Summary
December 6, 2012

DEC 2 1 2012

I.	**Company:**	Medtronic Sofamor Danek 1800 Pyramid Place Memphis, TN 38132 Telephone: (901) 396-3133 FAX: (901) 346-9738
II.	**Contact:**	Hetal Jawahar Thakker Senior Regulatory Affairs Specialist
III.	**Proprietary Trade Name:**	Kyphon® Express™ II Inflatable Bone Tamp
IV.	**Common Name:**	Inflatable Bone Tamp
V.	**Classification Name:**	Arthroscope (21CFR888.1100) Orthopedic Manual Surgical Instrument (21CFR 888.4540)
	Class:	II
	Product Code:	HRX, HXG

VI. Product Description

The Kyphon® Express™ II Inflatable Bone Tamps are designed for reduction of fractures. The main components are a coaxial dual lumen shaft, Y-Adapter with a port to connect the inflation syringe for inflation/deflation, and the inflatable balloon located at the distal tip.

VII. Indications for Use

The KYPHON Xpander™ II Inflatable Bone Tamps and Kyphon® Express™ II Inflatable Bone Tamps are intended to be used as a conventional bone tamp for the reduction of fractures and/or creation of a void in cancellous bone in the spine (including use during balloon kyphoplasty with a PMMA-based bone cement that is cleared for use in kyphoplasty procedures), hand, tibia, radius, and calcaneus.

VIII. Summary of Technological Characteristics

The fundamental scientific technology of the subject Kyphon® Express™ II Inflatable Bone Tamps is identical to the predicate KYPHON Xpander™ II Inflatable Bone Tamps.

Both the subject Kyphon® Express™ II Inflatable Bone Tamps and predicate KYPHON Xpander™ II Inflatable Bone Tamps consist of shaft, Y-Adapter and the inflatable balloon located at the distal tip. The Inflatable Bone Tamp is connected to an inflation syringe in order to inflate/deflate the balloon. Two radiopaque markers located at the distal and proximal end of the deflated balloon allow fluoroscopic visualization of the IBT during positioning prior to inflation. Once positioned, the balloon is inflated with contrast-media solution to create a cavity in the vertebral body, which may be subsequently filled with bone cement.

IX. Identification of the Legally Marketed Predicate Device Used to Claim Substantial Equivalence

In order to demonstrate substantial equivalence to legally marketed predicate devices, KYPHON Xpander™ II Inflatable Bone Tamp (K101864, SE Oct 14, 2010) is used as the predicate for the Kyphon® Express™ II Inflatable Bone Tamps.

X. Brief Discussion of the Non-Clinical Tests Submitted

Assessment of the device modifications have been completed in accordance with Medtronic design control processes. The Kyphon® Express™ II Inflatable Bone Tamps have the same design characteristics, packaging, use the same sterilization process, and are made of equivalent materials as the predicate KYPHON Xpander™ II Inflatable Bone Tamps. Mechanical testing and other verification/validation activities, including tolerance analyses were conducted to confirm that the modified device functions as intended and does not raise any new issues of safety or effectiveness.

XI. Conclusions Drawn from the Non-Clinical Tests

The subject and predicate Inflatable Bone Tamps are identical in terms of indications for use, intended use, performance specifications, and fundamental technological characteristics. A risk analysis and associated verification/validation testing was completed for the device modifications. Based on the risk analysis and additional supporting documentation provided in this premarket notification, Medtronic believes the subject Kyphon® Express™ II Inflatable Bone Tamps to be substantially equivalent to the legally marketed predicate KYPHON Xpander™ II Inflatable Bone Tamps.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Medtronic
% Medtronic Spine, LLC
Hetal Jawahar Thakker
Senior Regulatory Affairs Specialist
1221 Crossman Avenue
Sunnyvale, California 94089

December 21, 2012

Re: K123771
Trade/Device Name: Kyphon® Express™ II Inflatable Bone Tamps
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, HXG, NDN
Dated: December 6, 2012
Received: December 7, 2012

Dear Hetal Jawahar Thakker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Kyphon® Express™ II Inflatable Bone Tamps

Indications for Use:

The KYPHON Xpander™ II Inflatable Bone Tamps and Kyphon® Express™ II Inflatable Bone Tamps are intended to be used as a conventional bone tamp for the reduction of fractures and/or creation of a void in cancellous bone in the spine (including use during balloon kyphoplasty with a PMMA-based bone cement that is cleared for use in kyphoplasty procedures), hand, tibia, radius, and calcaneus.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number K123771